

protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof; and

an adjuvant selected from the group consisting of IL-12 and MF 59.

2. The vaccinating agent of claim 1 wherein said at least one majorly abundant extracellular product is M. tuberculosis 30 KD protein.

3. The vaccinating agent of claim 1 wherein said at least one majorly abundant extracellular product is a mixture of M. tuberculosis 32A KD protein, 30 KD protein, and 16 KD protein.

4. The vaccinating agent of claim 1 wherein said adjuvant is IL-12.

5. The vaccinating agent of claim 1 wherein said adjuvant is a mixture of IL-12 and MF 59.

6. A method for immunizing a mammalian host against an infectious pathogen of the genus Mycobacterium, said method comprising the steps of:

providing a vaccinating agent comprising at least a portion of at least one majorly abundant extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof, and an adjuvant selected from the group consisting of IL-12 and MF 59; and

introducing said vaccinating agent into said mammalian host to induce an effective immune response to subsequent infection by said infectious pathogen.

7. The method of claim 6 wherein said at least one majorly abundant extracellular product is M. tuberculosis 30 KD protein.

8. The method of claim 6 wherein said at least one majorly abundant extracellular product is a mixture of M. tuberculosis 32A KD protein, 30 KD protein and 16 KD protein.

9. The method of claim 6 wherein said adjuvant is IL-12.

10. The method of claim 6 wherein said adjuvant is a mixture of IL-12 and MF 59.

11. A vaccinating agent for use in promoting an effective immune response, in a mammalian host, against an infectious pathogen from the genus *Mycobacterium*, said vaccinating agent comprising:

at least one immunodominant epitope of at least one majorly abundant extracellular product selected from the group consisting of *M. tuberculosis* 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, [32A KD protein, 32B KD protein,] 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein, and respective analogs, homologs, and subunits thereof.

12. The vaccinating agent of claim 11 wherein said at least one majorly abundant extracellular product is *M. tuberculosis* 30 KD protein.

13. The vaccinating agent of claim 12 wherein said at least one immunodominant epitope is selected from the group consisting of *M. tuberculosis* 32A KD protein subunits having the amino acid sequences

Peptide Sequence	Seq. ID No.
W D I N T P A F E W Y D Q S G	106
P A F E W Y D Q S G L S V V M	107
P V G G Q S S F Y S D W Y Q P	110
G C Q T Y K W E T F L T S E L	114
K W E T F L T S E L P G W L Q	115
A N R H V K P T G S A V V G L	118
A V V G L S M A A S S A L T L	120
S A L T L A I Y H P Q Q F V Y	122
A I Y H P Q Q F V Y A G A M S	123
Q Q F V Y A G A M S G L L D P	124
G L L D P S Q A M G P T L I G	126
S Q A M G P T L I G L A M G D	127
N D P L L N V G K L I A N N T	134
N V G K L I A N N T R V W V Y	135

and respective analogs, homologs, and subunits thereof including single or multiple amino acid substitutions, deletions, insertions, and inversions.

14. An immunodiagnostic agent for use in promoting a detectable immune response in a mammalian host identifying an infectious pathogen from the genus *Mycobacterium*, said immunodiagnostic agent comprising:

at least one immunodominant epitope of at least one majorly abundant extracellular product selected from the group consisting of *M. tuberculosis* 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof.

15. The immunodiagnostic agent of claim 14 wherein said at least one majorly abundant extracellular product is *m. tuberculosis* 30 KD protein.

16. The immunodiagnostic agent of claim 15 wherein said at least one immunodominant epitope is selected from the group consisting of *M. tuberculosis* 32 KD protein subunits having the amino acid sequences

Peptide Sequence	Seq. ID No.
W D I N T P A F E W Y D Q S G	106
P A F E W Y D Q S G L S V V M	107
P V G G Q S S F Y S D W Y Q P	110
G C Q T Y K W E T F L T S E L	114
K W E T F L T S E L P G W L Q	115
A N R H V K P T G S A V V G L	118
A V V G L S M A A S S A L T L	120
S A L T L A I Y H P Q Q F V Y	122
A I Y H P Q Q F V Y A G A M S	123

Q	Q	F	V	Y	A	G	A	M	S	G	L	L	D	P	124
G	L	L	D	P	S	Q	A	M	G	P	T	L	I	G	126
S	Q	A	M	G	P	T	L	I	G	L	A	M	G	D	127
N	D	P	L	L	N	V	G	K	L	I	A	N	N	T	134
N	V	G	K	L	I	A	N	N	T	R	V	W	V	Y	135
I	A	N	N	T	R	V	W	V	Y	C	G	N	G	K	136

and respective analogs, homologs, and subunits thereof including single or multiple amino acid substitutions, deletions, insertions, and inversions.

17. A method of immunizing a mammalian host against an infectious pathogen of the genus *Mycobacterium*, said method comprising the steps of:

providing at least one immunodominant epitope of at least one majorly abundant extracellular product selected from the group consisting of *M. tuberculosis* 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof; and

introducing said at least one immunodominant epitope to said mammalian host to induce an effective immune response to subsequent infection by said infectious pathogen.

18. The method of claim 17 wherein said at least one majorly abundant extracellular product is *M. tuberculosis* 30 KD protein.

19. The method of claim 18 wherein said at least one immunodominant epitope is selected from the group consisting of *M. tuberculosis* 32A KD protein subunits having the amino acid sequences

Peptide Sequence														Seq. ID No.	
W	D	I	N	T	P	A	F	E	W	Y	D	Q	S	G	106
P	A	F	E	W	Y	D	Q	S	G	L	S	V	V	M	107

P	V	G	G	Q	S	S	F	Y	S	D	W	Y	Q	P	110
G	C	Q	T	Y	K	W	E	T	F	L	T	S	E	L	114
K	W	E	T	F	L	T	S	E	L	P	G	W	L	Q	115
A	N	R	H	V	K	P	T	G	S	A	V	V	G	L	118
A	V	V	G	L	S	M	A	A	S	S	A	L	T	L	120
S	A	L	T	L	A	I	Y	H	P	Q	Q	F	V	Y	122
A	I	Y	H	P	Q	Q	F	V	Y	A	G	A	M	S	123
Q	Q	F	V	Y	A	G	A	M	S	G	L	L	D	P	124
G	L	L	D	P	S	Q	A	M	G	P	T	L	I	G	126
S	Q	A	M	G	P	T	L	I	G	L	A	M	G	D	127
N	D	P	L	L	N	V	G	K	L	I	A	N	N	T	134
N	V	G	K	L	I	A	N	N	T	R	V	W	V	Y	135
I	A	N	N	T	R	V	W	V	Y	C	G	N	G	K	136

and respective analogs, homologs, and subunits thereof including single or multiple amino acid substitutions, deletions, insertions, and inversions.

20. A method for detecting the presence of an immune response in a mammal against a pathogen of the genus *Mycobacterium*, said method comprising the steps of:

providing at least one immunodominant epitope of at least one majorly abundant extracellular product selected from the group consisting of *M. tuberculosis* 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23 KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof;

administering said at least one immunodominant epitope to said mammal;

and

measuring the resultant immune response.

Mc67 21. The method of claim 20 wherein said at least one majorly abundant extracellular product is M. tuberculosis 30 KD protein.

22. The method of claim 21 wherein said at least one immunodominant epitope is selected from the group consisting of M. tuberculosis 32A KD protein subunits having the amino acid sequences

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W D I N T P A F E W Y D Q S G	106
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P V G G Q S S F Y S D W Y Q P	110
G C Q T Y K W E T F L T S E L	114
K W E T F L T S E L P G W L Q	115
A N R H V K P T G S A V V G L	118
A V V G L S M A A S S A L T L	120
S A L T L A I Y H P Q Q F V Y	122
A I Y H P Q Q F V Y A G A M S	123
Q Q F V Y A G A M S G L L D P	124
G L L D P S Q A M G P T L I G	126
S Q A M G P T L I G L A M G D	127
N D P L L N V G K L I A N N T	134
N V G K L I A N N T R V W V Y	135
I A N N T R V W V Y C G N G K	136

and respective analogs, homologs, and subunits thereof including single or multiple amino acid substitutions, deletions, insertions, and inversions.

Mc67 23. A process for producing a majorly abundant extracellular product selected from the group consisting of M. tuberculosis 110 KD protein, 80 KD protein, 71 KD protein, 58 KD protein, 45 KD protein, 30 KD protein, 24 KD protein, 23.5 KD protein, 23

KD protein, 16 KD protein, 14 KD protein, 12 KD protein and respective analogs, homologs, and subunits thereof, said process comprising the steps of:

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C77 transforming a host cell with a vector to form a transformed cell, said vector comprising a nucleic acid molecule encoding one of said majorly abundant extracellular products; and

culturing said transformed cell to thereby produce said majorly abundant extracellular product.

24. The process of claim 23 wherein said nucleic acid molecule encodes for the 30 KD M. tuberculosis protein.

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C87 25. The process of claim 24 which includes the additional step of recovering said majorly abundant extracellular product that is produced by culturing of said transformed cell.

26. The process of claim 24 wherein said vector comprises pSMT3 having a nucleic acid molecule comprising SEQ ID NO 36.

27. The process of claim 24 wherein said host cell is M. smegmatis or M. vaccae.

28. The process of claim 24 wherein said transformed cell is cultured at a temperature of 28°C.

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### Remarks

Due to the complexity of the Examiner's office action, the Applicants will address each rejection in the order presented and use the same paragraph numbering the Examiner used in her office action.

### Rejections under 35 U.S.C. § 112 second paragraph

4) The Examiner has rejected claim 26 under 35 U.S.C. § 112 second paragraph as being indefinite for failure to particularly point out and distinctly claim subject matter the